

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0330]

Display Date	9-30-05
Publication Date	10-3-05
Officer	R. LEPESMA
DPM	

Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods" dated September 2005. The draft guidance provides blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). The draft guidance is intended to help blood establishments ensure donor safety and the safety, purity, and potency of Platelets collected by an automated blood cell separator device. For the purpose of this document, Platelets collected by automated methods will be referred to by the product name "Platelets, Pheresis." The draft guidance contains recommendations for appropriate criteria for a biologics license application or supplement for manufacturing Platelets, Pheresis. When finalized, this draft guidance will replace the October 1988 "Revised Guideline for the Collection of Platelets, Pheresis."

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]* to ensure their

adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods" dated September 2005. The draft guidance provides blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). FDA has received new information since the issuance of the October 1998 "Revised Guideline for the Collection of Platelets, Pheresis." In addition, in recent years, many

improvements have been made in automated blood cell separator technology and blood cell counting methods. Automated blood cell separator devices are now capable of various plateletpheresis collection procedures including, but not limited to, collection of double and triple platelet components obtained during a single procedure; use of in-process leukocyte reduction; collection of concurrent plasma components; and collection of concurrent Red Blood Cell components. When finalized, the draft guidance will replace the October 1988 guideline.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

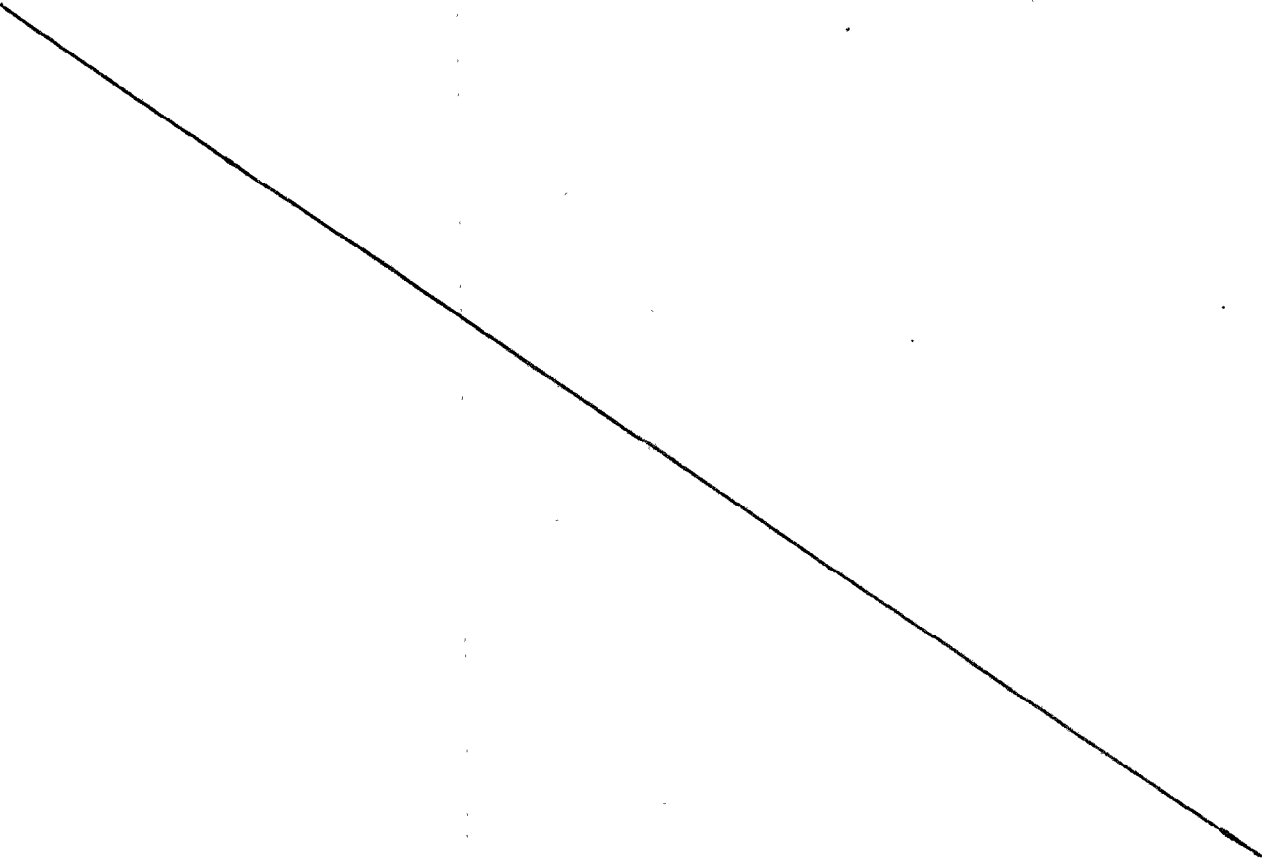
II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance are under FDA's regulations at parts 211, 601, 606, 610, and 640 (21 CFR parts 211, 601, 606, 610, and 640). Part 211, subpart J (Records and Reports) was approved under OMB control number 0910–0139; part 606, subpart I (Records and Reports) was approved under OMB control numbers 0910–0116 and 0910–0458. Sections 606.100(b) and (c), 606.110(a), 606.121, 606.122, 640.25, and 640.27 were approved under OMB control number 0910–0116; §§ 211.22, 211.80, 211.100(b), and 211.160 were approved under OMB control number 0910–0139; § 610.2 was approved under OMB control number

0910-0206; and §§ 601.12 and 610.60 were approved under OMB Control No. 0910-0338.

III. Comments

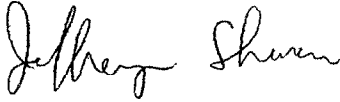
The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 9/12/05
September 12, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

